The bottom line is that I do not think single-use items should be reprocessed and I do not think there are adequate regulations now nor will there be in the future to regulate an industry of "reprocessors."

Your consideration of these matters is greatly appreciated.

Sincerely,

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December 3, 1999

Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Road
Rockville, MD 20850

RE: REPROCESSING OF SINGLE-USE MEDICAL DEVICES

Dear Mr. Spears:

This letter is in regard to the FDA's proposed new policy for regulating reprocessors of single-use medical devices. I am not able to attend the "town meeting" in Maryland and, therefore, wanted to submit my comments on this issue.

I am a practicing gastroenterologist working at Sacred Heart Medical Center in Eugene, Oregon. I use a large volume of disposable medical devices in my practice of gastroenterology such as biopsy forceps, snare devices for the removal of polyps and various instruments investigating the liver and biliary tree. My concern regards the potential spread of infectious diseases from these instruments. I am a believer in single-use instruments in this arena. I am concerned about cross-contamination of infectious organisms when these instruments are attempted to be reprocessed and I am also concerned about safety from the technical side with failure of the intended use for these instruments.

I know there are reprocessors who claim that they can reprocess these single-use devices, but I have serious doubts on the one hand, and on the other, I am quite concerned they are not going to be held accountable for quality reprocessing. In addition, most of these instruments are not designed